UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,006	05/09/2005	Mark Jason Heath Ellison	0702-044861	6712

28289 7590 09/27/2007

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,006	ELLISON ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/05 & 06/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-55 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 35, 40-41, 48, 51 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims **32 and 48** recite the broad recitation "solvent", and the claim also recites "in particular ethanol" which is the narrower statement of the range/limitation. Claims **35, 40-41 and 51** recite

the broad recitation of a class of agents or a process, and the claim also recites species within the said classes and examples of the process which is the narrower statement of the range/limitation.

Claim **55** provides for the use of an excipient, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim **55** is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Hallworth (EP 0750492).

Hallworth teach inhalation composition containing lactose pellets (col. 2, lines 10-

16). The final powder composition desirably contains 0.1 to 90% w/w, preferably 1-50% w/w of medicament relative to the weight of the lactose pellets (see [0012]). The final powder composition desirably contains 0.1 to 90% w/w and preferably 50-99% w/w lactose pellets (see [0023]).

Claims 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganderton et al (5,254,330).

Ganderton et al teach pharmaceutical excipients useful in dry powder inhalers. The preferred excipients are crystalline sugars such as **lactose**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28-51 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al (5,254,330) in view of Dahl et al (6,635,278).

Ganderton et al teach pharmaceutical excipients for dry powder inhalers including crystalline **lactose** sugars. The crystalline lactose is prepared by controlled crystallization from an aqueous medium. The solvents may be water and/or ethanol. The excess liquid is removed prior to drying (see columns 2-3). The said excipients comprise at least 80% and preferably at least 95% by weight of the novel carrier materials. The novel excipients may be admixed with any suitable pharmaceutical agents in order to provide a dry powder inhalant composition. Examples of suitable active agents for oral inhalation include steroids, anti-inflammatory agents, bronchodilators, anti-histamines, etc. The particle size of the active agents are in the range of 0.1 to 10 microns (see columns 3-4). The carrier particles have an average particle size of from 5.0 to 1000 microns (col. 2, lines 6-13). Ganderton et al lacks disclosure on process of granulation.

Dahl et al teach compositions comprising adenine and an alkaline excipient and methods of making the said composition. The process includes wet granulation, drying, milling, etc. The intragranular compositions are blended, mixed with a granulating solvent, dried and milled to obtain **granules** of a **desired particle size**. The intragranular composition is mixed with excipients. The excipients include an alkaline

excipient and one or more additional excipients such as **lactose**, or lactose monohydrate (col. 4, lines 13-30).

Dahl et al also teach that **unit dosage** formulations are made by **wet granulation** or by direct compression. The granulation provides granules of desired size. Wet granulation is accomplished using **water** or organic liquids such as acetone, or alcohols such as **ethanol**. **Fluid bed drying** is preferred over tray drying. The amount of solvent in the wet granulation process is usually about 5-50% of the weight. Lactose is used in an amount of about 50 to 70% of the total diluent. The wet components are milled through a #4 mesh screen and drier, and desired material is milled to desired geometric mean particle size.

Although the combined references do not recite the geometric diameters as claimed, they teach granulating and milling the excipients and active particles to the desired size.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Ganderton et al on preparing pharmaceutical carriers for inhalation such as lactose particles with teachings of Dahl et al on specific method of making excipients for inhalation including lactose granules as excipients made by method of wet granulation with a reasonable expectations of successfully preparing suitable and stable carrier/excipeints for effective delivery of active agents to the respiratory system. In other words, the claims would have been obvious because the technique for improving a particular process was part of the

ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
September 24, 2007